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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,318	06/21/2001	James W. Ayres	245-59204	6784

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KLARQUIST SPARKMAN, LLP
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EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/24/2003

64

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

	Application No.	Applicant(s)
	09/887,318	AYRES, JAMES W.
Examiner	Art Unit	
Simon J. Oh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 September 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-34, 58, 59, 73, 79, 80 and 82-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-34, 58, 59, 73, 79, 80 and 82-90 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

- 4) Interview Summary (PTO-413) Paper No(s) _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's request for continued examination, amendment, response, and declaration, all received on 08 September 2003.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-34, 58, 59, 73, 79, 80, and 82-90 under 35 U.S.C. 103(a) as being unpatentable over Van Balken *et al.* in view of Wong *et al.* is maintained.

Response to Arguments

Applicant's arguments filed 08 September 2003 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

It is the position of the examiner that the applicant's analysis, particularly regarding the three possible dosage forms envisioned by the applicant arising from the prior art, is based upon a narrow interpretation of both the claims and the prior art. It is the position of the examiner that

one of ordinary skill in the art, giving both the prior art and the claims in their present form their broadest reasonable interpretation, would find the claimed invention obvious in view of the prior art. See MPEP § 2111 and 2123.

The disclosure in Van Balken *et al.* concerning a permeable coating in order to effect a sustained release profile after a certain lag-time is broadly interpreted such that this feature is desirable in certain dosage forms, regardless of how this feature is achieved. The examiner has also relied upon the disclosure of Wong *et al.* to provide a method of sustained-release of a drug, which the examiner does not see as being particularly limited solely to the use of a permeable coating, in conjunction with the disclosed dosage form of Van Balken *et al.*, which is covered with a rupturable coating.

Although the Van Balken *et al.* and Wong *et al.* references are directed to differing methods of the differential release of a drug, the applicant has not set forth a convincing argument how such methods are necessarily counteractive to the point where an inoperable species is produced. It is clear from the disclosure of Van Balken *et al.* that the avoidance of a core with substantial swelling properties is done so for the purpose of preventing substantial swelling of said core to the point where the rupturing action of the outer coating becomes unpredictable or unreliable. However, it is the position of the examiner that the question how much or how little swelling material to include in such a core becomes one of routine experimentation by one of ordinary skill in the art for the purpose of optimization. Hence, the value of an insoluble belly band as a method to restrict and control the amount of fluid reaching a core comprising swellable materials, such as that taught by Wong *et al.*, becomes more apparent

to one of ordinary skill in the art for such optimization (See Wong *et al.*, Column 5, Lines 10-27).

It is the position of the examiner that it would be obvious to one of ordinary skill that, by the utilization of an insoluble belly band, a greater range of experimentation of the amount of swellable materials to be included in a core coated with the rupturable coating of Van Balken *et al.* It is further the position of the examiner that such experimentation can take place to the extent that a core with a significant extended-release profile could be formulated with a reasonable expectation of success, such a core being disclosed by Wong *et al.*

Regarding applicant's arguments concerning the instantly claimed band, it is the position of the examiner that the language of the claim is broad enough such that the sustained release core may be shaped in such a way so as to indicate where a band may be located on the instantly claimed tablet, such as by the creation of a circumferential indentation, with the band itself being overlaid on this indentation, thus satisfying the instant claim limitation.

The dosage form disclosed by Wong *et al.* may comprise a gastric-emptying delaying agent to facilitate retention in the stomach, which the examiner interprets as sufficiently reading on the instantly claimed limitation of an over-coating of an active ingredient on the dosage form. It is the position of the examiner that such an overcoating can be applied to what the examiner has determined to be an invention arising from the collective disclosure of the prior art. The examiner strongly disagrees with the applicant's interpretation of the Van Balken *et al.* patent, particularly with the notion that any immediate release of any biologically active ingredient somehow destroys the function of the invention of Van Balken *et al.* The administration of a

gastric-emptying delaying agent is effected by permeation of an overcoat, not by the rupture of an insoluble coating.

In the embodiments of the dosage forms arising from the collective disclosure of the prior art, compositions possessing release profiles exhibiting the lag time demonstrated in Van Balken *et al.* followed by the extended-release profile demonstrated in Wong *et al.* would be obvious to one of ordinary skill in the art, as relates to claim limitations in Claims 30-34. Even if the instant claim limitations regarding an n value greater than 0.70 for average dissolution from the time 10% of the active ingredient is released, until the time that 75% of the active ingredient is released is not explicitly disclosed in the prior art, it is the position of the examiner that it is obvious, based upon the written disclosures and figures of the prior art that one of ordinary skill could achieve such features through routine experimentation and optimization. The applicant has not set forth a sufficiently convincing argument showing otherwise.

The declarations submitted by the applicant and received by the Office on 08 September 2003 have been considered, but are determined by the examiner to be secondary evidence in the view of the *prima facie* case of obviousness that has been established by this Office. The examiner respectfully disagrees with the analyses of the prior art that have been given by Dr. Chen and Professor Ayres. In keeping with Office policy and under supervisory advisement, the examiner cannot give a significant weight to submitted declarations that are not supported by scientific data. It is the position of the examiner that, given the scope of the claims, as well as the disclosure of the prior art, the instant claims remain *prima facie* obvious.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

sjo


THURMAN K. PAGE
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